

Remarks

Claims 1-34 were previously pending in the subject application. By this amendment, the applicant has amended the specification and claims in the subject application. Specifically, claims 1, 4, and 5 have been amended, claims 2, 3, 7-11 and 15-23 have been cancelled and claims 24-34 have been withdrawn from consideration as being directed to non-elected subject matter. No new subject matter has been added by this amendment. Accordingly, claims 1, 4-6 and 12-14 are now before the Examiner for consideration.

The amendments set forth herein should not be interpreted to indicate that the applicant has agreed with, or acquiesced to, the rejections set forth in the outstanding Office Action. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicant wishes to thank the Examiner for the indication of allowable subject matter.

Initially, the Office Action has objected to the disclosure of the subject invention because of informalities. By this Amendment, the applicant has amended the specification at page 15, line 4, to delete reference to Appendix A. Also, the diameter of the ports has now been given in centimeters, in addition to inches. Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

Claim 8 has been objected to due to a typographical error. By this Amendment, the applicant has amended the typographical error in claim 8. Accordingly, reconsideration and withdrawal of this objection of claim 8 is respectfully requested.

Claims 1-3 and 5-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 3,583,602 (Gruber) in view of U.S. Patent No. 5,509,187 (Sperry *et al.*). The applicant respectfully traverses this grounds for rejection because there would be no motivation for a person skilled in the art to combine the teachings of these references to arrive at the current invention.

The Sperry *et al.* patent describes a method for irrigating wounds using an aerosol propellant to provide a stream of liquid wound cleansing solution which is substantially equivalent in volume and pressure to that generated by a 30 to 60 milliliter syringe having an 18 gauge needle.

In their Abstract, Sperry *et al.* state:

The method includes the steps of providing a propellant in the container which provides a pressure for propelling the wound cleansing solution through the valve, actuating the manually actuated valve to provide a stream of liquid wound cleansing solution which is substantially equivalent in volume and in pressure to that generated by a human hand-held 30 to 60 milliliter syringe having an 18 gauge needle mounted thereon and directing the stream toward the wound or abrasion to irrigate and cleanse the wound and/or abrasion.

The unique device of the subject invention facilitates the use of an entirely different (and highly advantageous) wound irrigation method. The device of the subject invention does not use an aerosol propellant; in contrast, the fluid exits the reservoir due to pressure applied manually to the walls of the compressible reservoir housing.

There would certainly be no motivation to modify the Sperry *et al.* device to make it compressible in view of the fact that the emphasis of Sperry *et al.* is to provide a device wherein a propellant pressurizes the device and expels the fluid. In fact, Sperry *et al.* specifically teach away from the subject invention by stating "it has been found that wound cleansing solution dispensed from such hand-held squeeze bottles is not as efficacious as the streams delivered from the 18 gauge needles carried by syringes heretofore utilized" (column 1, lines 30-34).

Although the device of the subject invention is clearly much simpler than the Sperry *et al.* device, this does not mean it is obvious. To the contrary, because it is simple and easy to use it is a tremendous improvement upon what has previously existed for wound irrigation. Moreover, the subject invention produces a dispersed stream of irrigation solution, whereas the Sperry *et al.* method is limited to a single concentrated stream of solution. The use of a dispersed stream has been found to be extremely effective in irrigating wounds. In this regard, please note that the unique and advantageous properties of the applicant's wound irrigation method have already been recognized by the issuance of U.S. Patent Nos. 5,830,197 and 6,468,253.

In their description of the preferred embodiments, Sperry *et al.* reiterate and emphasize that their device and method is specifically designed to mimic the stream of fluid produced by an 18 gauge needle. For example, Sperry *et al.* state:

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In the method for cleaning a wound or abrasion, a wound cleansing solution is provided which is formed into a pressurized stream which is substantially equivalent to that which is generated by a human hand operating a 30 to 60 milliliter syringe having an 18 gauge needle mounted thereon. The pressurized stream is created by the use of a prop gas. (emphasis added) (column 2 lines 38-42)

It was found that with the above parameters it is possible to provide a stream 126 of wound cleansing solution which has approximately the same characteristics as that produced by a hand-held 30 to 60 milliliter syringe provided with an 18 gauge needle. (emphasis added) (column 6 lines 1-5)

Thus, the Sperry *et al.* disclosure merely perpetuates the exact problem that the applicant's invention is designed to overcome. Clearly, the Sperry *et al.* method, which only serves to automate the same old ineffective procedure, would in no way suggest the applicant's unique device that facilitates the use of a large volume of sterile fluid applied in a dispersed stream.

The limitations of the Sperry *et al.* reference are not addressed by Gruber *et al.* The Gruber patent describes a device that is to be used in an entirely different field of endeavor from the current invention, and addresses an entirely different technical problem. Gruber specifically refers to containers used for dispensing "herbicides, insecticides, and fungicides," wherein uncontrolled drippage may result in harmful fluids being applied where they are not desired. Clearly, such concerns do not apply to a sterile fluid, and, thus, one skilled in the art would not be looking to the Gruber patent for guidance in solving problems associated with wound irrigation.

Therefore, initially, the applicant respectfully submits that the Gruber reference is improperly relied upon because it is from a non-analogous art. As expressed by the CCPA,

"[i]n resolving the question of obviousness under 35 USC §103, we presume full knowledge by the inventor of all the prior art in the field of his endeavor. However, with regard to prior art outside the field of his endeavor, we only presume knowledge from those arts reasonably pertinent to the particular problem with which the inventor was involved. The rationale behind this rule precluding rejections based on combination of teachings from references from non-analogous arts is the realization that an inventor could not possibly be aware of every teaching in every art." *In re Wood*, 599 F.2d 1032, 1036, 202 USPQ 171, 174 (CCPA 1979).

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In this regard, the CAFC has provided clear guidance as to the art which should be considered relevant to the inventor's field of endeavor:

We have reminded ourselves and the PTO that it is necessary to consider "the reality of the circumstances", *In re Wood*, 599 F.2d 1032, 1036, 202 USPQ 171, 174 (CCPA 1979) — in other words, common sense — in deciding in which fields a person of ordinary skill would reasonably be expected to look for a solution to the problem facing the inventor. . . The combination of elements from non-analogous sources, in a manner that reconstructs the applicant's invention only with the benefit of hindsight, is insufficient to present a *prima facie* case of obviousness. There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge can not come from the applicant's invention itself. *In re Oetiker*, 24 USPQ 2d 1443, 1446 (CAFC, 1992) (emphasis added).

In the current case, the applicant respectfully submits that the Gruber invention is in a different field of endeavor and addresses entirely different problems than those that have been solved by the current invention, and is thus non-analogous art.

Furthermore, there would not be any motivation for the skilled artisan to modify the teachings of Sperry *et al.* in view of Gruber. First, Sperry *et al.* describes an aerosol spray bottle; therefore, Gruber's teachings with respect to avoiding drippage from a squeeze bottle are not applicable to the Sperry *et al.* device at all. Moreover, Sperry *et al.* repeatedly emphasize the ability to mimic the stream produced by an 18 gauge needle. This, of course, is precisely the approach that has been rejected by the current applicants in arriving at the instant invention.

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, neither reference contains a suggestion to combine these teachings to arrive at the current invention. It is only the applicants' disclosure that provides such a teaching, and the applicant's disclosure cannot be used to reconstruct the prior art for a rejection under §103. This was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Srock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of

themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, “[b]oth the suggestion and the expectation of success must be founded in the prior art” *In re Dow Chemical Co., supra* at 1531. In the references cited in support of the §103 rejection, one finds neither.

An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Sponnoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969).

The applicant has provided a unique device, having a compressible reservoir, a sterile fluid, and multiple ports, which facilitates an admittedly simple, but very advantageous, wound irrigation method. The method has been patented in the applicant's parent applications. Were it not for the new method, there would be no reason to modify the prior art to arrive at the device that is currently claimed. Accordingly, the applicant respectfully submits that the device, as now claimed, is not obvious. Thus, applicants respectfully request that this rejection under 35 USC §103 be reconsidered and withdrawn.

Claims 12 and 13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Gruber in view of Sperry *et al.* as applied to claim 1 above, and further in view of U.S. Patent No. 5,133,701 (Han). The applicant respectfully traverses this grounds for rejection because the cited references, alone or in combination, provide no teaching or suggestion of the current invention.

The shortcomings of Gruber and Sperry *et al.* have been discussed above. The Han reference, although disclosing a backsplash shield, does not cure the aforementioned defects in the primary references. Accordingly, the applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103.

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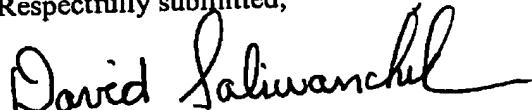
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In view of the foregoing remarks and amendment, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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